

§ 520.445b

21 CFR Ch. I (4-1-03 Edition)

(3) *Limitations.* Not to be used for more than 28 consecutive days; withdraw 15 days before slaughter; as sole source of chlortetracycline and sulfonamide.

[57 FR 37323, Aug. 18, 1992, as amended at 67 FR 78355, Dec. 24, 2002]

**§ 520.445b Chlortetracycline powder (chlortetracycline hydrochloride or chlortetracycline bisulfate).**

(a) *Specifications.* Chlortetracycline powder contains not less than 15 milligrams per gram chlortetracycline hydrochloride, or chlortetracycline bisulfate equivalent to 25.6, 64 or 102.4 grams per pound (56.4, 141 or 225.6 milligrams per gram) chlortetracycline hydrochloride.

(b) *Sponsors.* See No. 053389 in § 510.600(c) of this chapter for conditions of use as in paragraph (d) of this section; No. 053501 for conditions of use as in paragraph (d)(4) of this section; No. 000010 for conditions of use as in paragraphs (d)(4)(i)(A) and (B) and (d)(4)(ii) through (iv) of this section; Nos. 017519 and 059130 for conditions of use as in paragraphs (d)(4)(i)(A) and (B) and (d)(4)(ii) and (iii) of this section.

(c) *Related tolerances.* See § 556.150 of this chapter.

(d) *Conditions of use.* (1) Use as chlortetracycline hydrochloride in drinking water as follows:

(i) *Swine*—(A) *Amount.* Ten milligrams per pound of body weight daily in divided doses.

(1) *Indications for use.* Control and treatment of bacterial enteritis (scours) caused by *Escherichia coli* and bacterial pneumonia associated with *Pasteurella* spp., *Actinobacillus pleuropneumoniae* (*Hemophilus* spp.), and *Klebsiella* spp.

(2) *Limitations.* Prepare a fresh solution twice daily; as sole source of chlortetracycline; administer for not more than 5 days.

(B) [Reserved]

(ii) [Reserved]

(2) Use as chlortetracycline hydrochloride in a drench or drinking water as follows:

(i) *Calves*—(A) *Amount.* Ten milligrams per pound of body weight daily in divided doses.

(1) Control and treatment of bacterial enteritis (scours) caused by *E.*

*coli* and bacterial pneumonia (shipping fever) associated with *Pasteurella* spp., *A. pleuropneumoniae* (*Hemophilus* spp.), and *Klebsiella* spp.

(2) *Limitations.* Prepare fresh solution daily; as sole source of chlortetracycline; administer for not more than 5 days; do not slaughter animals for food within 24 hours of treatment; do not administer this product with milk or milk replacers; administer 1 hour before or 2 hours after feeding milk or milk replacers; a withdrawal period has not been established in pruruminating calves; do not use in calves to be processed for veal.

(B) [Reserved]

(ii) [Reserved]

(3) [Reserved]

(4) The following uses of chlortetracycline hydrochloride or chlortetracycline bisulfate in drinking water or drench were reviewed by the National Academy of Sciences/National Research Council (NAS/NRC) and found effective:

(i) *Chickens*—(A) *Amount.* 200 to 400 milligrams per gallon.

(1) *Indications for use.* Control of infectious synovitis caused by *Mycoplasma synoviae*.

(2) *Limitations.* Prepare fresh solution daily; as sole source of chlortetracycline; do not use for more than 14 days; do not slaughter animals for food within 24 hours of treatment; do not use in laying chickens.

(B) *Amount.* 400 to 800 milligrams per gallon.

(1) *Indications for use.* Control of chronic respiratory disease and air-sac infections caused by *M. gallisepticum* and *E. coli*.

(2) *Limitations.* Prepare fresh solution daily; as sole source of chlortetracycline; do not use for more than 14 days; do not slaughter animals for food within 24 hours of treatment; do not use in laying chickens.

(C) *Amount.* One thousand milligrams per gallon.

(1) *Indications for use.* Control of mortality due to fowl cholera caused by *Pasteurella multocida* susceptible to chlortetracycline.

(2) *Limitations.* See paragraph (d)(4)(i)(A)(2) of this section.

(ii) *Growing turkeys*—(A) *Amount.* 400 milligrams per gallon.

(1) *Indications for use.* Control of infectious synovitis caused by *M. synoviae*.

(2) *Limitations.* Prepare fresh solution daily; as sole source of chlortetracycline; do not use for more than 14 days; do not slaughter animals for food within 24 hours of treatment.

(B) *Amount.* 25 milligrams per pound of body weight daily.

(1) *Indications for use.* Control of complicating bacterial organisms associated with bluecomb (transmissible enteritis, coronaviral enteritis).

(2) *Limitations.* Prepare fresh solution daily; as sole source of chlortetracycline; do not use for more than 14 days; do not slaughter animals for food within 24 hours of treatment.

(iii) *Swine*—(A) *Amount.* 10 milligrams per pound body weight daily in divided doses.

(B) *Indications for use.* Control and treatment of bacterial enteritis (scours) caused by *E. coli* and *Salmonella* spp. and bacterial pneumonia associated with *Pasteurella* spp., *Actinobacillus pleuropneumoniae* (*Hemophilus* spp.), and *Klebsiella* spp.

(C) *Limitations.* Prepare fresh solution daily; as sole source of chlortetracycline; do not use for more than 5 days; for 000010 and 017519 do not slaughter animals for food within 5 days of treatment; for 053501 do not slaughter animals for food within 24 hours of treatment.

(iv) *Calves, beef cattle, and nonlactating dairy cattle*—(A) *Amount.* 10 milligrams per pound daily in divided doses.

(B) *Indications for use.* Control and treatment of bacterial enteritis (scours) caused by *E. coli* and *Salmonella* spp. and bacterial pneumonia (shipping fever complex) associated with *Pasteurella* spp., *A. pleuropneumoniae* (*Hemophilus* spp.), and *Klebsiella* spp.

(C) *Limitations.* Prepare fresh solution daily; use as a drench; as sole source of chlortetracycline; do not use for more than 5 days; do not slaughter animals for food within 24 hours of treatment; do not use in lactating cattle; do not administer this product with milk or milk replacers; administer 1 hour before or 2 hours after feeding milk or milk replacers; a withdrawal period has not been established in preruminating

calves; do not use in calves to be processed for veal.

[57 FR 37324, Aug. 18, 1992; 57 FR 42623, Sept. 15, 1992; 58 FR 61015, Nov. 19, 1993; 59 FR 39439, Aug. 3, 1994; 60 FR 26827, May 19, 1995; 60 FR 47052, Sept. 11, 1995; 62 FR 27691, May 21, 1997; 62 FR 35076, June 30, 1997; 62 FR 60656, Nov. 12, 1997; 64 FR 37673, July 13, 1999; 65 FR 10706, Feb. 29, 2000; 66 FR 35898, July 10, 2001; 67 FR 78355, Dec. 24, 2002]

#### § 520.445c Chlortetracycline tablets and boluses.

(a) *Specifications.* Each tablet/bolus contains 25, 250, or 500 milligrams of chlortetracycline hydrochloride.

(b) *Sponsors.* See No. 000010 in § 510.600(c) of this chapter for the 250-milligram chlortetracycline hydrochloride bolus; see No. 053501 for the 25-milligram tablet and the 500 milligram bolus.

(c) *Related tolerances.* See § 556.150 of this chapter.

(d) *National Academy of Sciences/National Research Council NAS/NRC status.* The conditions of use specified in this section were NAS/NRC reviewed and found effective. Applications for these uses need not include effectiveness data as specified in § 514.111 of this chapter but may require bioequivalency and safety information.

(e) *Conditions of use. Calves*—(1) *Amount.* One 250 milligram bolus per 50 pounds of body weight twice a day for 3 to 5 days.

(i) *Indications for use.* Treatment of bacterial enteritis (scours) caused by *Escherichia coli* and bacterial pneumonia associated with *Pasteurella* spp., *Klebsiella* spp., and *Hemophilus* spp.

(ii) *Limitations.* Administer bolus directly by mouth or crush and dissolve in milk or water for drenching or bucket feeding; if no improvement is noted after 3 days of treatment, consult a veterinarian; do not use for more than 5 days; do not administer within 24 hours of slaughter.

(2) *Amount.* One 25 milligram tablet for each 5 pounds of body weight every 12 hours daily for 3 to 5 days.

(i) *Indications for use.* Control and treatment of bacterial enteritis (scours) caused by *E. coli* and *Salmonella* spp. and bacterial pneumonia associated with *Pasteurella* spp., *Hemophilus* spp., and *Klebsiella* spp., susceptible to chlortetracycline.